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Award Number: W81XWH-12-1-0004

TITLE: An Independent, Prospective, Head to Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury

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REPORT DATE: March 2013

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
March 2013	Annual Report	1 March 2012- 28 February 2013

4. TITLE AND SUBTITLE
An Independent, Prospective, Head to Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-1-0004

5c. PROGRAM ELEMENT NUMBER
- - -

6. AUTHOR(S)
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5d. PROJECT NUMBER
- - -

5e. TASK NUMBER
- - -

5f. WORK UNIT NUMBER
- - -

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Medical College of Wisconsin
Milwaukee, WI 53226

8. PERFORMING ORGANIZATION REPORT NUMBER
- - -

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)
- - -

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
- - -

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES
- - -

14. ABSTRACT

The current study involves a head to head comparison of the reliability and clinical validity of four neurocognitive assessment tools (NCAT's) for the acute neurocognitive assessment, tracking cognitive recovery, and informing clinical management after mild traumatic brain injury (mTBI). The specific NCAT's under study include: the Automated Neuropsychiatric Assessment Metric (ANAM), AXON Sports, Defense Automated Neurobehavioral Assessment (DANA), and Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT). The study design involves both a Sports Concussion Arm and Civilian mTBI Arm. Both study arms are fully operational with data collection underway, with steady progress toward recruitment of mTBI/concussion participants and controls. In the first phase of data collection, we have enrolled more than 400 athletes in the baseline study phase, and 38 injured and control participants in the postinjury protocol. A new online e-consent platform developed as part of this project has been highly effective. Obstacles to recruitment in the civilian mTBI (hospital emergency dept.) arm have been identified and alternate strategies developed. Overall, the study is on target with respect to statement of work, timeline and budget. With ongoing recruitment of injured and control participants, we anticipate having informative data on our specific aims relevant to the NCAT's as part of future annual reports.

15. SUBJECT TERMS
Mild traumatic brain injury; concussion; neurocognitive assessment

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	12	19b. TELEPHONE NUMBER *(include area code)* - - -

Annual Technical Report

An Independent, Prospective, Head to Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury (mTBI)

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1. INTRODUCTION

The current study involves a head to head comparison of the reliability and clinical validity of four neurocognitive assessment tools (NCAT's) for the acute neurocognitive assessment, tracking cognitive recovery, and informing clinical management after mild traumatic brain injury (mTBI). The specific NCAT's under study include: the Automated Neuropsychiatric Assessment Metric (ANAM), AXON Sports, Defense Automated Neurobehavioral Assessment (DANA), and Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT). The study design involves both a Sports Concussion Arm and Civilian mTBI Arm.

This project aligns directly with the Department of Defense's high-ranking priority to validate evidence-based methods for the assessment and evaluation of traumatic brain injury. Specifically, this study will benefit the DoD by informing operational medicine and policy as to the implementation of neurocognitive testing to a) diagnose the acute cognitive effects of mTBI, b) measuring recovery in cognitive functioning after mTBI, and c) clinical decision making regarding a warfighter's fitness to return to duty after mTBI.

This study is uniquely designed to address gaps in the literature on the efficacy of neurocognitive testing in the assessment of mTBI through the following aims:

SA 1 NCAT Reliability: Determine and compare the test-retest reliability of the candidate neurocognitive test batteries over serial administrations and a time course consistent with that typical of a clinical setting of sport-related concussion and civilian mTBI.
SA 2 NCAT Predictive Validity: Determine and compare the predictive validity of the candidate neurocognitive test batteries administered during the acute period (within 24 hours) in predicting the time course of clinical recovery 8, 15, 45 days after sport concussion and civilian mTBI.
SA 3 NCAT Sensitivity and Specificity: Determine and compare the sensitivity and specificity of the candidate neurocognitive test batteries in reliably detecting cognitive impairments in athletes with concussion and civilians with mTBI who are otherwise self-reporting a complete symptom recovery and would be potentially cleared for return to activity 24 hours and 8, 15 and 45 days postinjury.

2. BODY:

Progress on Statement of Work:

This study is fully IRB approved and operational. Data collection is underway in both the Sports Concussion Arm and the Civilian mTBI Arm of the project. In the Sports Concussion Arm, preseason baseline testing was conducted prior to the fall and winter sports seasons for soccer (men/women), field hockey (women), ice hockey, and wrestling. Baseline testing for football, lacrosse, rugby and soccer is scheduled for spring 2013. The postinjury protocol for both the Sports Concussion Arm and Civilian mTBI Arm is fully implemented and underway. In the first phase of data collection, we do not have sufficient sample sizes to analyze data on the specific aims relevant to the NCATs, but based on our progress we fully anticipate having informative data and analysis for future reports.

Please see Table 1 for the status of our performance specific to tasks identified in our formal Statement of Work. Please see below for a detailed summary of key research accomplishments and the status of tasks identified in the formal statement of work for this project.

Table 1. Status of tasks in Statement of Work (SOW)

Task	Task Description	Status
1	Finalize protocol and informed consent documents and submit to Medical College of Wisconsin (PI Site) IRB and authorizing Dept. of Defense (DoD) IRB for review and approval.	Complete
2	Establish sound, efficient system for project fiscal management and program evaluation.	Complete
3	Obtain final IRB approval (Mos. 1-3)	Complete
4	Recruit and fill all study research staff positions (Mos. 1-3)	
5	Finalize operational plan for all phases of the study; work with investigative team, emergency department and participating institutions on efficient plan for recruitment, enrollment, and implementation (Mos. 1-3)	Complete
6	Full investigator meeting held. (Mos. 1-3)	Complete
7	Implement study operational plan at PI site and data collection sites. (Mos. 1-9)	Complete
8	Conduct baseline testing and follow-up protocol data collection (Mos. 3-30).	Ongoing
9	Conduct annual investigator meetings to review progress, interim data analysis, need for course correction, operational plan for remainder of study period. (Yrs 1-3)	Ongoing
10	Complete required progress reports with sponsor and other authorities. (Yrs 1-3)	Ongoing
11	Data analysis, interpretation, reporting, dissemination. (Mos. 30-36, post-study)	Future
12	Present findings at DoD forums and other scientific meeting relevant to TBI and sport related concussion.	Future
13	Publish findings in peer-reviewed scientific journals.	Future
14	Consult with our key collaborators to identify venues within the DoD for dissemination of our key findings that have direct clinical relevance to the clinical assessment and management of mTBI in OEF/OIF warriors and veterans.	Future

Recruitment and Participation:

In the sports concussion arm, recruitment is on schedule. As of 1/15/2013, we have baseline tested 362 athletes, including 256 high school athletes and 106 college athletes. These figures do not include football, which will provide the overwhelmingly largest number of concussions studied and will be involved in data collection in the 2013 and 2014 seasons. Compared to all other sports (soccer, lacrosse ice hockey, field hockey, rugby, wrestling), football will provide the large quantity of both baseline testing participants and concussed athletes.

Overall, we have baseline tested 97.8% of consented athletes, which represents 70% of all eligible athletes (based on their participation in target sports at their institution). The baseline participant sample so far is 79% male, 21% female based on the sports under study. At the college level, we have consented and baseline tested 99% of athletes identified as eligible for the study. Given our success at the college level, we are recruiting two additional colleges to join the study for the fall sports season. Among the high schools, we have baseline tested 97.3% of consented athletes, which represents 62.4% of all eligible athletes at all schools. These figures are consistent with our previous multi-center studies, in which participation and compliance is higher among college athletes than high school athletes. We are implementing a number of strategies to increase the level of participation in baseline testing at participating high schools.

During the fall sports season (excluding football 2012) and partial winter season, 10 concussed athletes were enrolled in and completed the post-injury research protocol. In addition, 10 matched controls completed the protocol. No athletes (concussed or control) were lost to follow-up (attrition 0%). The concussed and control athlete samples are tightly matched on age, grade point average (GPA), institution, sport and team of participation, and baseline score on the Wechsler Test of Adult Reading (WTAR), as laid out in our matching methodology.

In the Civilian mTBI Arm, a total of 21 patients have been consented (12 mTBI, 9 controls) during the first 4 months of data collection. Among the mTBI sample, attrition has been an issue, as 50% (n=6) of those consented have been lost to follow-up after the 24 hour assessment point. Five mTBI participants have completed the protocol and one remains active. We are implementing a number of strategies to increase recruitment and reduce attrition in the Civilian mTBI Arm, as outlined below in the discussion of challenges and strategic responses. Only one control participant has been lost from follow-up.

A significant percentage of mTBI patients from the emergency department (ED) at our level I trauma center are found to not be eligible because they fail to meet the study's inclusion/exclusion criteria. Specifically, common exclusions include: presence of Axis I psychiatric disorder, currently on psychotropic or narcotic medication, under the influence of alcohol or drugs in the ED, or the patient is beyond 24 hours since their injury. We are exploring strategies to increase enrollment of eligible patients, as outlined below.

Preliminary Findings:

As noted earlier, our sample of participants (injured and control) enrolled in the post injury protocol during the first several months of data collection is not yet large enough to perform formal statistical analysis on the reliability, validity, sensitivity and specificity of the NCAT's in the assessment of sport-related concussion and civilian mTBI. Therefore, we will analysis and present those data in future reports, based on our planned sample sizes.

We have, however, accumulated large amounts of normative data on NCAT's from the baseline phase of the Sports Concussion Arm that are informative as to the psychometrics and practical use of the NCAT's. Tables 2-4 compare baseline normative test performance by high school and college athletes on each of the NCAT's in the Sports Concussion Arm of the study. Our early analysis of available baseline data indicated no statistically significant group differences on

ANAM, AXON, or ImPACT. The main implication is that all three NCAT's psychometrically behave similarly among high school and college athletes, meaning that different versions of each NCAT would not be required for use based on the different age and education level of the population being tested. Similar analysis on the psychometrics will be conducted as we continue to collect large normative data sets on the NCAT's over the course of the study.

Table 2. Comparison of baseline normative data for high school and college participants on ANAM.

ANAM	High School (N = 193)			College (N = 55)				
Subtest	M	SD	95% CI (Lower, Upper)	M	SD	95% CI (Lower, Upper)	*t*	*p*
Simple RT	237.58	25.18	(221.58, 253.58)	240.75	34.45	(211.95, 269.55)	-0.24	0.815
Code Substitution	53.75	17.89	(42.38, 65.11)	54.88	11.58	(45.19, 64.56)	-0.16	0.877
Procedural RT	91.25	24.83	(75.47, 107.03)	106.75	13.54	(95.43, 118.07)	-1.60	0.126
Math Processing	15.92	9.01	(10.19, 21.64)	20.25	9.35	(12.44, 28.06)	-1.04	0.313
Matching to Sample	34.42	17.54	(23.27, 45.56)	39.50	16.27	(25.90, 53.10)	-0.65	0.522
Code Substitution-Delay	41.08	16.07	(30.87, 51.29)	44.25	24.46	(23.80, 64.70)	0.35	0.730
Simple RT 2	230.92	36.92	(207.46, 254.38)	246.00	29.63	(221.23, 270.77)	-0.96	0.348
Go/No-Go RT	314.67	34.87	(292.51, 336.82)	298.75	32.07	(271.93, 325.57)	1.03	0.316
Go/No-Go Commissions	7.75	2.49	(6.17, 9.33)	8.88	2.59	(6.71, 11.04)	-0.98	0.343
Go/No-Go Omissions	1.25	2.80	(-.53, 3.03)	0.88	2.10	(-.88, 2.63)	0.32	0.751
Go/No-Go D'	3.42	1.08	(2.73, 4.11)	4.00	1.31	(2.91, 5.09)	-1.09	0.292

*all subtests except Go/No-Go present Throughput scores

Table 3. Comparison of baseline normative data for high school and college participants on AXON.

AXON	High School (N = 193)			College (N = 55)				
Subtest	M	SD	95% CI (Lower, Upper)	M	SD	95% CI (Lower, Upper)	*t*	*p*
Processing Speed	105.99	5.51	(105.21, 106.77)	106.23	5.02	(104.87, 107.58)	-0.28	0.777
Attention	106.32	5.47	(105.54, 107.09)	107.73	5.31	(106.29, 109.17)	-1.70	0.091
Learning	100.41	6.76	(99.45, 101.37)	101.31	6.47	(99.57, 103.06)	-0.88	0.380
Working Memory Speed	103.55	6.09	(102.68, 104.41)	103.87	6.76	(102.05, 105.70)	-0.34	0.733
Working Memory Accuracy	103.11	7.73	(102.01, 104.20)	104.38	8.88	(101.98, 106.78)	-1.04	0.298

*Standard scores with M = 100, SD = 10

AXON	High School (N = 193)			College (N = 55)				
Subtest	M	SD	95% CI (Lower, Upper)	M	SD	95% CI (Lower, Upper)	*t*	*p*
Processing Speed	280.07	41.29	(274.21, 285.94)	280.09	38.04	(269.81, 290.37)	0.00	0.998
Attention Speed	440.06	61.63	(431.31, 448.81)	425.80	58.60	(409.96, 441.64)	1.53	0.127
Learning Accuracy	69.88	7.41	(68.83, 70.93)	70.69	7.22	(68.74, 72.64)	-0.72	0.473
Working Memory Speed	631.42	116.97	(614.77, 648.07)	630.22	136.32	(593.37, 667.07)	0.07	0.949
Working Memory Accuracy	93.53	5.17	(92.81, 94.27)	93.84	6.02	(92.21, 95.46)	-0.37	0.713

*Raw scores (speed in ms; accuracy in %)

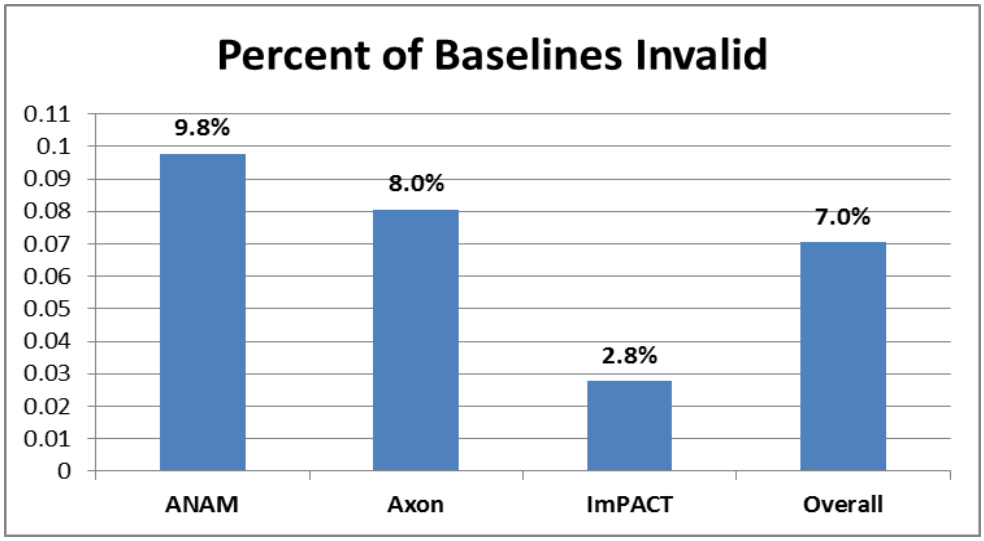
Table 4. Comparison of baseline normative data for high school and college participants on ImPACT.

ImPACT	High School (N = 156)			College (N = 49)				
Composite Score/Subtest	M	SD	95% CI (Lower, Upper)	M	SD	95% CI (Lower, Upper)	*t*	*p*
Verbal Memory Composite	85.30	9.60	(83.78, 86.82)	87.02	9.90	(84.18, 89.86)	-1.09	0.279
Word Memory % Correct	94.61	5.76	(93.70, 95.52)	96.01	4.72	(94.65, 97.37)	-1.54	0.124
Symbol Match # Correct-Hidden	6.43	1.88	(6.14, 6.73)	6.63	1.83	(6.11, 7.16)	-0.66	0.508
ThreeLetters % Correct	89.96	12.50	(87.98, 91.93)	92.11	11.68	(88.75, 95.46)	1.07	0.287
Visual Memory Composite	77.89	12.23	(75.96, 79.83)	78.76	11.85	(75.35, 81.16)	-0.44	0.664
Design Memory % Correct	82.06	12.48	(80.09, 84.03)	80.40	13.62	(76.49, 84.31)	0.80	0.427
XO # Correct (Memory)	8.85	2.11	(8.51, 9.18)	9.27	1.83	(8.74, 9.79)	-1.25	0.213
Visual Motor Speed Composite	38.28	6.38	(37.27, 39.29)	39.67	6.78	(37.73, 41.62)	-1.32	0.190
XO # Correct (Interference)	115.55	7.11	(114.43, 116.68)	117.10	6.41	(115.26, 118.94)	-1.36	0.175
Three Letters # Correct	15.89	4.00	(15.26, 16.52)	16.69	4.22	(15.48, 17.90)	-1.21	0.229
Reaction Time Composite	0.58	0.06	(.57, .59)	0.57	0.08	(.55, .59)	1.21	0.229
XO Correct RT (Interference)	0.48	0.06	(.47, .49)	0.47	0.06	(.45, .48)	1.74	0.084
Symbol Match Correct RT (Visible)	1.57	0.30	(1.52, 1.61)	1.52	0.31	(1.43, 1.61)	1.07	0.286
Color Match Correct RT	0.73	0.14	(.71, .76)	0.74	0.15	(.69, .78)	-0.11	0.912
Impulse Control Composite	5.93	4.41	(5.23, 6.62)	6.16	4.20	(4.96, 7.37)	-0.33	0.744
XO # Incorrect (Interference)	5.65	4.22	(4.98, 6.32)	5.96	4.15	(4.77, 7.15)	-0.45	0.651
Color Match Commissions	0.28	0.54	(.19, .36)	0.20	0.46	(.08, .33)	0.84	0.403

Quality Control and Validity of Baseline Test Results

In both military and sports settings, there is a great deal of discussion and speculation over the potential for baseline test results to be rendered invalid for a variety of reasons (e.g., unsatisfactory test conditions, motivational factors, psychometric properties of the NCAT's themselves). We have examined this issue in our early baseline data collection in the Sports Concussion Arm of the study and find the rate of invalid baselines to actually be reasonably low. For all NCAT's we have used the test developer's specific criteria for determining results to be invalid. Using those criteria, Figure 1 presents the percentage of all baseline assessments to be invalid for each NCAT.

Figure 1. Percent of baseline administrations determined invalid for each NCAT in the sports concussion arm.



At this early juncture, ImPACT has the lowest (2.8%, 6 of 217) and ANAM the highest (9.8%, 24 of 246) rate of invalid results. AXON had a 8.0% invalid rate (21 of 261). These data are considered preliminary from a select group of athletes in sports baseline tested to date, but indicate effective quality control associated with our research operation and provide some encouraging news regarding the relative infrequency of invalid test results compared to other reports in the literature. Future analysis will look at factors associated with invalid baseline test results.

Challenges and Strategic Response:

We continue to make refinements to optimize the operation of this study. Over the course of year one, we have identified a number of potential challenges and successfully developed strategies to address those issues, including:

- *NCAT Engineering*: We have discovered that it takes significant manpower and resource to troubleshoot local and remote operational issues and idiosyncracies of the NCATs. We have created manuals to standardize our response to these issues across the NCATs.
- *High School Baseline Enrollment*: To increase the percentage of eligible participants who consent for participation and complete baseline testing, we are meeting with the Athletic Director, head coach, and certified athletic trainer at each school to engage participation in the study. In many schools, we are also attending sport parent meetings to provide information about the study and to engage their interest. These strategies have been effective in prior studies.
- *Invalid Baseline Testing*: Although at a relatively low rate, we developed a standardized approach to handling of all repeat baselines in a uniform way across all NCATS.
- *ED mTBI Enrollment and Attrition*: As indicated above, a relatively high percentage of mTBI patients fail to meet our inclusion/exclusion criteria, mostly due to alcohol or narcotics on board. We are expanding our RA coverage hours in the ED to increase enrollment and exploring other strategies to capture acute mTBI patients that will likely meet our inclusion/exclusion criteria. Although we planned for 25% attrition in the ED sample, the observed rate in a small sample so far is closer to 33-50%. We also have a formal request into our office of compliance to provide our IRB-approved financial incentives to ED patients on the day of their assessment (instead of mailed to them at a later date) in an attempt to maximize incentive for recruitment and reduce attrition. We have implemented telephone and electronic reminders to all patients and are exploring other tactics (e.g., remote assessments) to reduce attrition.

Project Budget Management

This project is running slightly ahead of budget through 12/31/2012, due to the backend nature of heavy research activities and expenses slated for the latter end of the year. We anticipate that we will remain on budget over the course of the full funding period. Key personnel receiving pay from this research effort including:

- Michael McCrea, PhD (PI)
- Brooke Lerner, PhD (Co-I)
- Jennifer Hill, MS (Project Coordinator)

- Ashley Laroche (Research Assistant)
- Robyn Furger (Research Assistant)
- Senior Scientific Advisory Panel: William Barr, Kevin Guskiewicz, Thomas Hammeke, Christopher Randolph

3. KEY RESEARCH ACCOMPLISHMENTS:

In addition to securing IRB approval and implementing the infrastructure and operational resources to support this study, the following milestones have been achieved:

Sports Concussion Arm:

- Formal engagement with 13 high schools and colleges.
- Web-based eConsent process/platform IRB approved and fully operational.
- All NCAT's successfully engineered for remote testing at sports sites.
- Fully integrated REDCap database constructed for data storage and management; full interface with statistical software in place for seamless transfer and data analysis.
- Baseline testing completed on 362 athletes (97.8% of consented) participating in soccer, field hockey, wrestling, ice hockey and lacrosse.
- Strong performance of our methodology for tightly matching control participants to concussed athletes.
- Preliminary data analysis on various psychometric aspects of NCAT baseline test results.
- Good quality control with low rate of invalid baselines (7.0% overall)
- Injury protocol completed on 10 concussed athletes and 10 matched controls in fall sports season (excluding football 2012).
- Baseline testing for spring sports underway.

ED mTBI Arm:

- Electronic ED activity monitoring implemented to identify possible mTBI patients.
- Fully integrated REDCap database constructed for data storage and management; full interface with statistical software in place for seamless transfer and data analysis.
- Research assistant deployed to ED for patient recruitment, acute assessments.
- ED coverage expanded for additional weekday and weekend coverage for screening and recruitment.
- In 4 months, 141 potential mTBI patients identified through electronic medical record (EMR) observation; 43 were approached as they met inclusion/exclusion criteria upon initial EMR review; 21 patients consented
- 12 mTBI patients enrolled in study protocol; 5 completed postinjury protocol, 1 active in follow-up, 6 lost to follow-up.
- 9 control patients enrolled in study protocol; 3 completed postinjury protocol, 5 active in follow-up, 1 lost to follow-up.
- Outreach to MCW urgent care and walk in clinic network to increase recruitment of acute mTBI patients.
- Formal request in place for institutional approval (both IRB and compliance) of alternative methods of participant compensation to enhance recruitment and reduce attrition.

4. REPORTABLE OUTCOMES:

In year one of the project, data collection is fully underway, but we do not yet have sufficient data for formal peer-reviewed publications on reportable outcomes relevant to our specific scientific aims. We are planning to submit abstracts for poster presentations on secondary aims from this study at the 2012 meeting of the American Academy of Clinical Neuropsychology (AACN), which will be published in abstract form in The Clinical Neuropsychologist (TCN) in the summer of 2012. We anticipate additional publications and professional presentations with further data collection.

Major reportable outcomes already achieved from this study relate to research informatics. We have successfully built and implemented (with IRB approval) an online, electronic informed consent platform (eConsent) that supports the Sports Concussion Arm of this study. This is a replicable paradigm that will serve other investigators and research projects effectively in the future. In addition, we have built a highly sophisticated and fully operational REDCap database for data storage. The database is fully secured and makes for highly efficient data entry, storage, and transfer to statistical software packages, with optimal quality control mechanisms. This engineering approach has already been replicated in our other research projects and will serve our database management needs well into the future.

We are also leveraging this project by exploring collaborative opportunities with other DoD-funded researchers, including data sharing to mutually support multiple projects.

5. CONCLUSION:

In summary, this project is on target with respect to statement of work, timeline, budget and progress toward achieving our specific technical and scientific aims. Obstacles to recruitment in the civilian mTBI (hospital emergency dept.) arm have been identified and alternate strategies developed. With ongoing recruitment of injured and control participants in both the Sports Concussion Arm and the Civilian mTBI Arm, we anticipate having informative data on our specific aims relevant to the NCAT's and other critical research questions at the time of our next annual report.

6. REFERENCES:

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AXON Sports Computerized Cognitive Assessment Tool (CCAT). AXON Sports, Inc. Corporate office: 2100 Stewart Avenue, Suite 201, Wausau, WI 54401, Website: http://www.axonsports.com/

Defense Automated Neurobehavioral Assessment (DANA). AnthroTronix, Inc. Corporate Offices: 8737 Colesville Road, Suite L-203, Silver Spring, MD 20910. Website: http://www.anthrotronix.com/.

Immediate Post-concussion Assessment and Cognitive Test (ImPACT). ImPACT Applications, Inc. Corporate Office: 2000 Technology Drive, Suite 150, Pittsburgh, PA 15219. Website: http://impacttest.com/

7. APPENDICES:

No appendices. Tables and figures embedded in text of report.

8. SUPPORTING DATA:

See tables and figures embedded in text of report.